

Application Number 10/731,868
Responsive to Office Action mailed February 20, 2007

RECEIVED
CENTRAL FAX CENTER

MAR 05 2007

REMARKS

This Amendment responsive to the Office Action mailed September 5, 2006, and is submitted in response to the Notification mailed February 20, 2007. This Amendment is a substitute for the Amendment filed December 4, 2006, which was found to be not fully responsive by the Examiner as indicated in the Notification. The Notification indicated Applicant's previous Amendment failed to specifically point out support in the original disclosure for each of the newly presented claim limitations. More particularly, the Notification stated that the newly added limitations in claims 1, 25, 26 and 29 were not addressed, or were addressed by referring to paragraph numbers not found in the application as originally filed.

This Amendment is modified relative to the previous Amendment to address the omissions identified in the Notification. In particular, the reference to paragraphs [0064] and [0065] in the previous Amendment has been modified to refer to paragraphs [0051] and [0052], which were present in the Application as originally filed. However, Applicant notes that the previous Amendment did specifically point out support in the original disclosure for the amendment to claim 1. This discussion can be found in the second paragraph of page 8 of the present Amendment.

Applicant has amended claims 1, 8 and 12, canceled claims 18-23 and added claims 24-29. Claims 1-17 and 24-29 are pending, and of these, claims 13 and 14 are currently withdrawn.

Claim Rejection Under 35 U.S.C. § 112

The Office Action mailed September 5, 2006 rejected claims 22 and 23 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicant has canceled claims 22 and 23; therefore, the rejection of claims 22 and 23 under 35 U.S.C. § 112 is now moot.

The Office Action mailed September 5, 2006 also rejected claim 8 under 35 U.S.C. § 112, second paragraph for lacking proper antecedent basis for the term "the lead." Applicant amended claim 8 such that it depends from claim 7, which provides proper antecedent basis for the term "the lead." Applicant respectfully requests the Examiner withdraw the rejection to claim 8 under 35 U.S.C. § 112.

Application Number 10/731,868
Responsive to Office Action mailed February 20, 2007

Claim Rejection Under 35 U.S.C. § 102

The Office Action mailed September 5, 2006 rejected claims 1-3, 5-10, 12, 15-17, 22 and 23 under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 6,648,914 to Berrang et al. (hereinafter "Berrang"). The Examiner also rejected claims 1-4, 7, 15, 22 and 23 under 35 U.S.C. § 102(e) as being anticipated by U.S. Pub. No. 2003/0109903 Berrang et al. (hereinafter "Berrang Application").

Applicant has amended claim 1 to recite placing a substantial portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp. Support for the amendment to claim 1 may be found at least in FIGS. 2-5 and the accompanying text. For example, FIG. 5 clearly depicts a substantial portion of IMD 12 located within the pocket 30. Claims 22 and 23 have been canceled.

The applied references fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provide no teaching that would have suggested the desirability of modification to include such features.

Page 2 of the Office Action mailed September 5, 2006 argued that both Berrang and Berrang Application disclose forming a pocket behind the incision for placement of the implant. However, the characterization of Berrang and Berrang Application is inconsistent with the invention as recited by claim 1. For example, claim 1 recites making an incision in a scalp of a head of a patient to create a scalp flap, after separating the scalp flap from the skull, separating a portion of the remainder of the scalp adjacent to the fold from the skull to create a pocket adjacent to the fold and between the scalp and the skull, and placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp. In this manner, claim 1 defines the pocket as being adjacent to the fold and between the scalp and the skull. Notably, claim 1 precludes the scalp flap itself from being considered part of the pocket. The language in the Office Action mailed September 5, 2006 of "behind the incision" suggests that the Examiner may consider Berrang and Berrang Application to disclose a flap that creates a pocket. In the event the Examiner continues to cite either Berrang or Berrang Application in a rejection of claim 1, Applicant respectfully requests clarification as to which portion of the FIGS. 3 is considered to disclose a pocket as defined by Applicant's claims.

Application Number 10/731,868
Responsive to Office Action mailed February 20, 2007

In any case, neither Berrang nor Berrang Application discloses creating a pocket adjacent to the fold and between the scalp and the skull as recited by claim 1. In fact, neither Berrang nor Berrang Application demonstrate that there is any separation whatsoever between a scalp and behind a fold as recited in claim 1. Applicant notes that neither Berrang nor Berrang Application discusses any such separation.

Nonetheless, Applicant has amended claim 1 to further distinguish Applicant's invention from Berrang and Berrang Application. Specifically, Applicant amended claim 1 to recite placing a substantial portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp. Thus the subject matter of claim 1 is further distinguished from Berrang and Berrang Application, which clearly fail to disclose placing a substantial portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp as recited by claim 1.

Because Berrang and Berrang Application fail to disclose a pocket, or placing a substantial portion of a low-profile implantable medical device in the pocket as recited by claim 1, Berrang and Berrang Application each fail to anticipate the Applicant's invention as recited in claim 1. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 1-10, 12 and 15-17 under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103

The Office Action mailed September 5, 2006 rejected claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Berrang or Berrang Application. Applicant respectfully traverses the rejection to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

As discussed previously in this Amendment, Berrang and Berrang Application individually and collectively fail to disclose or suggest every element of independent claim 1. The rejection of claim 11 fails to overcome the deficiencies of Berrang and Berrang Application with respect to the elements of claim 1. For example, it would not have been obvious to one of

Application Number 10/731,868
Responsive to Office Action mailed February 20, 2007

ordinary skill in the art from the disclosures of Berrang and Berrang Application to separate a portion of the remainder of the scalp adjacent to the fold from the skull after separating the scalp flap from the skull to create a pocket adjacent to the fold and between the scalp and skull, and place at least a portion of a low-profile implantable medical device in such a pocket, as recited by independent claim 1. Because claim 11 is dependent on claim 1, the subject matter of claim 11 would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claim 11 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

New Claims

Applicant has added claims 24-29 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. As one example, the applied references fail to disclose or suggest making an incision in a scalp at a top of a head of a patient to create a scalp flap at the top of the head of the patient, separating the scalp flap from a skull of the patient, wherein the scalp flap is attached to the remainder of the scalp by a fold, after separating the scalp flap from the skull, separating a portion of the remainder of the scalp adjacent to the fold from the skull to create a pocket adjacent to the fold and between the scalp and the skull and placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp, as recited by claim 28.

As another example, the applied references fail to disclose or suggest making an incision in a scalp of a head of a patient to create a scalp flap, separating the scalp flap from a skull of the patient, wherein the scalp flap is attached to the remainder of the scalp by a fold, after separating the scalp flap from the skull, separating a portion of the remainder of the scalp adjacent to the fold from the skull to create a pocket adjacent to the fold and between the scalp and the skull; and placing all of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp as recited by claim 26.

RECEIVED
CENTRAL FAX CENTERApplication Number 10/731,868
Responsive to Office Action mailed February 20, 2007

MAR 05 2007

No new matter has been added by the new claims. For example, support for new claims 24 and 28 may be found from, e.g., paragraphs [0027]-[0029] and FIGS. 2-11. Support for new claims 25, 26 and 29 may be found from, e.g., paragraph [0052] and FIGS. 2-5 and the accompanying text. Support for new claim 27 may be found from, e.g., paragraph [0051] and claim 12 of the Applicant's specification as filed.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Applicant does not acquiesce with any of the Examiner's current rejections or characterizations of the prior art, and reserve the right to further address such rejections and/or characterizations. No fees are believed due at this time. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

By:

MARCH 5, 2007
SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Daniel T. Lund
Name: Daniel T. Lund
Reg. No.: 58,614